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10/518,915

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EXAMINER

CLARK, AMY LYNN

ART UNIT

PAPER NUMBER

1655

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 10/518,915 | Applicant(s) YANO ET AL. | |
| | Examiner AMY L. CLARK | Art Unit 1655 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4, 6, 8-13 and 15-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4, 6, 8-13 and 15-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10 March 2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on 03/18/2009 with the amendment of claims 4, 6, 8-13, 15-18 and newly added claims 19-25.

Any rejection found in the previous Office Action and not repeated herein has been withdrawn based upon Applicants' amendments to the claims.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 4, 6, 8-13 and 15-25 are currently under examination.

Claim Objections

Claims 12 and 19 are objected to because of the following informalities: the phrase “f said subject” in line 2 contains a typographical error. The phrase “inhibiting wrinkles cause by” contains the wrong verb conjugation. Appropriate correction is required.

Claim Rejections - 35 USC § 102

Claims 4 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Uehara et al. (N1, JP 2000-119156, Translation provided herein) (newly applied as necessitated by amendment).

Uehara teaches a method of decreasing pigmentation in a guinea pig brought wherein the pigmentation is induced by irradiation of guinea pig skin with UV-B light comprising administering a composition comprising an extract of coix seed (*Coix lacryma-jobi*) (See paragraphs 0039 and 0040), which reads on inhibiting photoaging in a subject in need thereof and also reads on inhibiting wrinkles caused by photoaging because the composition clearly

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treats symptoms of photoaging when applied to the skin of a subject. Uehara further teaches a method of preventing skin dullness and pigmentation comprising administering a composition comprising coix-seed extract in an amount of 0.01% or a composition comprising chamomile extract (See the Examples).

Claims 4, 11, 12 and 18 remain rejected under 35 U.S.C. 102(b) as being anticipated by Garlen et al. (B*, 4,707,354).

Garlen teaches a method for treating skin comprising covering said skin with a layer of a sunscreen, protectant, moisturizing, dermatological composition consisting essentially of a formulation comprising less than 1 wt % silk powder (See claim 8). Garlen further teaches that the method for administration of such compositions to human skin to provide rehydration and nearly complete screening of cancer-causing actinic radiation (See abstract) and protects mature skin from cell damage and dehydration due to exposure to sunlight (See "Field of the Invention"), which reads on "inhibits photoaging" and "inhibiting wrinkles caused by photoaging", since blocking sunlight inhibits photoaging and inhibits wrinkle formation caused by photoaging.

Therefore, the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

Claims 4, 7, 8, 11, 14 and 15 remain rejected and newly added claims 16-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sei et al. (S*, JP 2002-128651 A), in view of Andre-Jean et al. (T*, JP 07-145067 A) (newly applied to claims 16-25 based upon the fact that these are newly added claims).

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Sei teaches a photoaging inhibitor (See abstract) that has an anti-aging effect and demonstrates a high improvement effect to wrinkles (See paragraph 0077) in the form of a topical composition for administration to the skin comprising ginseng extract in an amount of 0.00001 - 10 mass %, or 0.0001 to 5% (See paragraph 0008), coix seed extract, a seaweed extract (See paragraph 0037), chamomile extract (See paragraph 0012) in an amount of 0.0001 to 3% (See paragraph 0018), silk protein (which is a type of silk extract) and a zizyphi fructus extract (See paragraph 0039). Sei further teaches that the skin care composition is administered, topically, to a mouse and that the skin care composition is administered, *in vitro*, to human skin cells (See Examples paragraphs 0041-0063). Please note that by applying a composition that is capable of inhibiting photoaging leads to inhibition of angiogenesis, since angiogenesis is stimulated by UV exposure. Therefore, the effect of inhibiting angiogenesis would be intrinsic to a photoaging inhibitor.

Andre-Jean teaches a cosmetic composition for treating skin comprising 0.1-15 wt.% hydroglycol extract of alga such as Chlorella (See abstract). Andre-Jean further teaches that the therapeutic method by these cosmetics protects the skin and hair from the exteriors, such as an oxidizer, sunrays, and a staining agent, against the element which does adverse action, maintains the organization of the skin or hair, and aims at improving the quality of the skin (See paragraph 0038), which reads on inhibiting photoaging. Andre-Jean further teaches examples of administering the cosmetic composition to the skin (See Example 1 beginning with paragraph 0040).

The method of using the referenced composition is not expressly taught as a method of inhibiting wrinkles caused by photoaging. However, the instantly claimed process is a **one-step process** of applying to skin a composition comprising .1-15 wt.% hydroglycol extract of alga such as Chlorella. Thus, the functional effect of protecting keratinous fiber from extrinsic damage is intrinsic to the method of using the composition taught by Andre-Jean particularly since the amount of an extract of chlorella administered to the skin falls within the range claimed by Applicant.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method taught by Sei by administering a composition comprising da zhao extract, ginseng extract, chamomile extract, chlorella extract, coicis semen extract, and silk extract, which are all ingredients that have the same functional effect of inhibiting photoaging and inhibiting wrinkles caused by photoaging. Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the instantly claimed ingredients of da zhao extract, ginseng extract, chamomile extract, chlorella extract, coicis semen extract, and silk extract for their known benefit of inhibiting photoaging and inhibiting wrinkles caused by photoaging since each claimed ingredient is well known in the art for the same purpose, as useful for weight loss and for the following reason:

It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980); *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960); and *Ex parte*

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Quadranti, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992). As the court explained in Crockett, the idea of combining them flows logically from their having been individually taught in prior art. Therefore, since each of the references teach that da zhao extract, ginseng extract, chamomile extract, chlorella extract, coicis semen extract, and silk extract, are useful for inhibiting photoaging and inhibiting wrinkles caused by photoaging, it would have been obvious to combine these ingredients with the expectation that such a combination would be effective for inhibiting photoaging and inhibiting wrinkles caused by photoaging. Thus, combining them flows logically from their having been individually taught in prior art.

From the teachings of the references, it is apparent that one of ordinary skill in the art one would have been motivated to combine da zhao extract, ginseng extract, chamomile extract, chlorella extract, coicis semen extract, and silk extract to provide a beneficial composition for the expected benefit of inhibiting photoaging and inhibiting wrinkles caused by photoaging because at the time the invention was made, the instantly claimed ingredients da zhao extract, ginseng extract, chamomile extract, chlorella extract, coicis semen extract, and silk extract were known to be useful for inhibiting photoaging and inhibiting wrinkles caused by photoaging, and since the ingredients and mode of administering the ingredients, which are one and the same as those claimed by Applicants, was known in the art at the time the invention was made. Thus the combined composition of da zhao extract, ginseng extract, chamomile extract, chlorella extract, coicis semen extract, and silk extract would have been expected to be even more effective for inhibiting photoaging and inhibiting wrinkles caused by photoaging because the claimed ingredients were all useful for this purpose, as clearly taught by the above references.

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Finally, one of ordinary skill in the art would have had a reasonable expectation of success to combine the following ingredients for inhibiting photoaging and inhibiting wrinkles caused by photoaging to gain the benefits of individual components as part of a composition for inhibiting photoaging and inhibiting wrinkles caused by photoaging: da zhao extract, ginseng extract, chamomile extract, chlorella extract, coicis semen extract, and silk extract, to provide a beneficial composition for the expected benefit of inhibiting photoaging and inhibiting wrinkles caused by photoaging because at the time the invention was made, these ingredients were well known promoting weight loss.

Moreover, it would have been obvious to one of ordinary skill in the art, one would have been motivated and one would have had a reasonable expectation of success at the time the invention was made to modify the referenced composition because it would have been well in the purview of one of ordinary skill in the art practicing the invention to pick and choose a concentration of da zhao extract, ginseng extract, chamomile extract, chlorella extract, coicis semen extract, and silk extract because at the time the invention was made, da zhao extract, ginseng extract, chamomile extract, chlorella extract, coicis semen extract, and silk extract were known to be useful for promoting inhibiting photoaging and inhibiting wrinkles caused by photoaging and the references provided herein teach amounts of the ingredients claimed. Therefore, adjusting the amount of da zhao extract, ginseng extract, chamomile extract, chlorella extract, coicis semen extract, and silk extract would have been obvious to enhance the effect of these ingredients. Thus, the claimed invention is no more than the routine optimization of a result effect variable.

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Based upon the beneficial teachings of the cited references, the skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Response to Arguments

Applicants' arguments with regards to the rejection under 35 U.S.C. 102(b) have been carefully considered but are not deemed to be persuasive of error in the rejection.

Applicants argue that Garlen teaches silk powder and does not teach how to obtain the silk powder and that it is known in the art that silk powder and silk extract are different kinds of silk derivatives. Applicants further argue that the silk powder taught by Garlen is an auxiliary component rather than an active ingredient.

This is not found persuasive because silk powder is a type of silk extract, particularly when read with the broadest reasonable interpretation of extract. If Applicants wish to further define what type of silk extract is being used in the composition employed in the instantly claimed method to show that it is indeed different than what is claimed by Garland, then it is suggested that Applicants recite what particular type of extract is being used in Applicants claimed method. With regards to the argument that silk extract is an auxiliary material, Garland clearly teaches that silk powder is employed in a composition that has the instantly claimed effect and does not state that the silk powder is merely an auxiliary material. Further, Applicants

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use open claim language which does not prevent other active ingredients to be present in a composition comprising silk extract.

Applicants' arguments with regards to the rejection under 35 U.S.C. 103(a) have been carefully considered but are not deemed to be persuasive of error in the rejection.

Applicants argue that Sei teaches that chamomile and coicis semen are auxiliary ingredients. Applicants further argue that Sei, Andre-Jean and Garlen do not teach de zao or silk extract.

However, this is not found persuasive because Sei teaches that the instantly claimed ingredients are active ingredients in the composition. Further, Applicants use open claim language which does not prevent other active ingredients to be present in a composition comprising Applicants' instantly claimed ingredients. Sei expressly teaches "silk protein" in paragraph 0039, which is a type of silk extract, and "zizyphi fructus extract", also in paragraph 0039, which is synonymous with da zao. Applicants are invited to further define their invention by closing the claim language and by further describing the type of extract Applicants' are employing (for example: aqueous, ethanol, hexane, organic, etc.) used in the method.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMY L. CLARK whose telephone number is (571)272-1310.

The examiner can normally be reached on Monday to Friday between 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ALC
Examiner, AU 1655

/Christopher R. Tate/
Primary Examiner, Art Unit 1655

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